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EXAMINER	
MEHTA, PARIKHA SOLANKI	
ART UNIT	**PAPER NUMBER**
3737	
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11/03/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/766,707	FLOYD ET AL.	
	Examiner	Art Unit	
	PARIKHA S. MEHTA	3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-12 and 14-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12 and 14-38* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 August 2008* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed. The following title is suggested: Method and system for positioning a medical instrument at multiple angles relative to an imaging probe.

Claim Objections

2. Claims 1-8 and 16-23 are objected to because of the following informalities:

Claim 1 recites "said support", whereas the preceding claim language sets forth multiple supports. As such, it is unclear exactly which element "said support" is referring to.

Claim 4 recites “the medical device support”, whereas the preceding claim language sets forth a plurality of medical device supports. As such, it is unclear exactly which element is referred to by “the medical device support".

Claim 8 fails to further limit the structure of the claimed invention. Claim 8 sets forth limitations for the medical device, which is not positively set forth as part of the inventive apparatus.

Claim 16 recites “the diameter of said medical device" without proper antecedent basis; the preceding claim language does not sufficiently limit the medical device to one having an elliptical or round cross-section of constant size along its longitudinal axis (i.e., the difference between a straight needle and a drill bit), therefore it cannot inherently have a diameter.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 18, 19, 30 and 31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the

specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, the claims recite a guide having a predefined closing angle, and a closing angle which is calibrated. The present disclosure makes no discussion of how to predefine and/or calibrate the closing angle, and as such a skilled artisan would not be reasonably apprised of how to achieve these limitations.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 16-27 and 35-37 are rejected under 35 U.S.C. 102(b) as being anticipated by Pruter (US Patent No. 6,296,614), hereinafter Pruter ('614), of record.

Regarding claims 16-23 and 35-37, Pruter ('614) discloses a method of releasable attaching a needle to an ultrasound probe, including steps for positioning the needle having a round cross-section along a longitudinal axis of the probe by inserting it into a releasable needle guide (col. 2 lines 23-28), clamping the needle with respect to the probe so that an angle of attack of the needle remains constant with respect to a proximal end of the probe (col. 5 lines 22-28), wherein the clamping is partly controlled by a slidably coupled latch having a dimension keyed to the diameter of the needle (col. 5 lines 1-9) , wherein the latch comprises a wedge portion defining the dimension (Figs. 2 & 4). Pruter ('614) additionally discloses steps for generating an image of structures below the surface of an object over which the ultrasound moves, the image generation resulting from the ultrasonic waves emitted by the probe (col. 5 lines 19-23). Pruter ('614) slides a proximal end of the needle toward the surface of the object along a trajectory predictable as a result of the image, and continues to slide the proximal end of the needle along the trajectory to a position below the surface of the object, after which Pruter ('614) releases the needle from the probe while the probe remains in the patient (col. 5 lines 19-34). As the guide trajectory along which the needle of Pruter ('614) travels is fixed and the needle has a finite depth to which it can be inserted in the object, the reference guide meets the limitations of having a predefined closing angle calibrated to a depth below the surface of the object as claimed. A portion of the latch of Pruter ('614) contains a ramp, and the reference latch is positioned transverse to the longitudinal axis of the probe (Figs. 2 & 4). The bracket of Pruter ('614) is adapted to accept, one at a time, a plurality of

needle guides accepting different gauge needles (col. 5 lines 1-9). Pruter ('614) slides the needle along the trajectory to a focal point under the skin of a patient (col. 5 lines 19-26).

Regarding claims 24-27, Pruter ('614) discloses a needle guide comprising a releasable latch 6 configured to mate with a proximate end of an ultrasonic probe 4, a channel 38 configured to accept the longitudinal axis of an elongated needle 12, wherein the channel lies along the longitudinal axis of the ultrasound probe when the guide is mated with the latch, the channel defining a pre-established closing angle with respect to a location below the surface of an object, and a slide configured to traverse the channel, the slide applying controlled clamping force on the needle (col. 2 lines 33-50).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1-12 and 14, 15, 28-34 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pruter (US Patent No. 6,296,614), hereinafter Pruter ('614), of record, in view of Hayakawa (US Patent No. 5, 967, 985), hereinafter Hayakawa ('985).

Regarding claims 1-12, 14, 15 and 28-34, Pruter ('614) teaches a method and apparatus for guiding a needle while attached to an ultrasound transducer probe, wherein the guide includes a latch 22, a longitudinal and cross-sectionally round channel/guide 40 ("a longitudinal seating area") capable of accepting a needle ("medical device" or "rod"), and a latch 92 that is capable of sliding over the needle and applying controlled clamping force on the needle (Figs. 2 & 4). The present recitation of a "latch" is

interpreted to constitute "any of various devices in which mating mechanical parts engage to fasten but usually not to lock something," as per the common definition of the term "latch" set forth by Merriam Webster. The system of Pruter ('614) includes a bracket 6 that attaches to the probe (Fig. 2, col. 2 lines 37-39), wherein the bracket is adapted to accept, one at a time, a plurality of needle guides ("medical device supports") of varying gauge (col. 9 lines 1-5). Pruter ('614) further includes slots for fitting over a transducer (Fig. 2), a flexible tab 36, a tapered wedge 38 and a pivot point at its proximal end (Examiner notes that, so long as an element can be moved in a pivotal fashion at some arbitrary location, it is reasonably considered to have "a pivot point" at that location). Pruter ('614) additionally teaches the latch to include a funnel shaped body 40 and an overhang portion on the latch 92 (Fig. 4) that prevents the needle from becoming disengaged from the guide without first moving the latch to an open position, wherein the overhang constitutes pivoting means for controlling the release of the needle as claimed. Pruter ('614) sets forth steps for advancing a biopsy needle through the guide while the guide is attached to the transducer, and for separating the transducer assembly from the needle after insertion (col. 5 lines 19-34). Pruter ('614) teaches that the clamping mechanism is specifically adapted for the particular size of the medical device (col. 5 lines 1-9), i.e. that it is keyed to the dimension/gauge of the needle. The enclosed needle guide channel of Pruter ('614) constitutes the claimed slide, wherein "slide" is interpreted to mean "a guiding surface along which something slides" as set forth by Merriam Webster.

Pruter ('614) does not teach the inclusion of multiple device supports having different attack angles. In the same field of endeavor, Hayakawa ('985) teaches that it is helpful to have multiple guides of differing attack angle in order to more accurately position a needle with respect to the depth of the target within the patient (col. 5 lines32-48, col. 27 line 65 – col. 28 line 3). It would have been obvious to one of ordinary skill in the art to have modified Pruter ('614) to include multiple guides, each guide having a different angle of attack, in view of the teachings of Hayakawa ('985).

Regarding claim 38, Pruter ('614) substantially teaches all features of the present invention as previously discussed for claim 35. Pruter ('614) does not expressly teach that the selection of a needle guide comprises removing the needle guide from a plurality of needle guides having different angles of attack, wherein the plurality of guides are held by a common bond. In the same field of endeavor, Hayakawa ('985) teaches the provision of multiple needle guides having different angles of attack such that the user can select a guide having the appropriate angle for achieving the desired insertion depth (col. 5 lines32-48, col. 27 line 65 – col. 28 line 3). The multiple guides of Hayakawa ('985) attach to the clamping mechanism in the same way, and as such are interpreted to be "held by a common bond" as claimed. It would have been obvious to one of ordinary skill in the art to have modified Pruter ('614) to

select the needle guide from a set of guides having different attack angles as taught by Hayakawa ('985) in order to more accurately position the needle with respect to the target position within the patient.

Response to Arguments

8. Applicant's arguments filed 14 Aug 2008 have been fully considered but they are not persuasive.

Regarding Applicant's arguments regarding the prior rejection of claims 18, 19, 30 and 31 under 35 U.S.C. 112, neither the disclosure nor the drawings sufficiently describe or illustrate the "predefined closing angle" in such a way as to notify one of ordinary skill in the art as to what exactly defines such an angle. Figure 11, as referred to in the arguments, shows no angle whatsoever, and paragraph 25 of the disclosure merely describes the closing angle as being an angle between the proximal end of the guide and some unspecified, seemingly arbitrary portion of the medical device. The guide 30, as described in paragraph 25 and shown in Figures 1-3, has multiple edges and surfaces that are capable of forming different angles with various parts of the medical instrument. The term "closing angle" is not one which is commonly used in the art to the extent that a skilled artisan would be able to ascertain exactly what this term means. As such, the previous rejection of claims 18, 19, 30 and 31 is in fact proper and maintained herein.

Regarding Applicant's arguments that Pruter ('614) lacks a plurality of instrument supports (Remark p. 14 & 15, claims 1 and 28), this argument is moot in view of the new grounds of rejection presented herein as necessitated by the amendments of 14 Aug 2008.

Regarding Applicant's arguments that Pruter ('614) lacks a latch which fits over a rod and has a tapered wedge portion for positioning below a rod (Remarks p. 14, claim 9), the reference was found to disclose a funnel shaped opening 40 having a triangular groove 38, as cited in the prior Office Action, and this feature is interpreted to constitute the claimed tapered wedge. It appears that Applicant is attempting to limit the tapered wedge and other features of the latch in terms of elements which are not positively set forth as part of the claimed invention (i.e., the rod); these limitations are considered as nothing more than intended use recitations which do not limit the actual structure of the claimed invention and are therefore not given significant patentable weight.

Regarding Applicant's arguments that Pruter ('614) lacks a slidably coupled latch and a latch having a wedge portion configured to create a dimension (Remarks p. 14 & 15, claims 16 & 35), since the latch allows the needle to slide through the guide while clamped, the latch is "slidably coupled" as claimed. The groove 38 of Pruter ('614) a wedge portion defining the dimension keyed to the diameter of

the needle. Regarding the latch having a dimension keyed to the diameter of the medical device, the latch of Pruter ('614) must inherently have a dimension which is complementary to the gauge of the needle, i.e. that renders the latch capable of accepting the needle, as it would not otherwise be operable to clamp and control the position of the needle as disclosed. The term "keyed' cannot be interpreted so narrowly as to only mean that the dimensions of the latch and needle diameter are exactly matched; "keyed" only requires that the two dimensions render the elements operationally compatible. Furthermore, Pruter ('614) specifically sets means for specifically adapting the clamping mechanism for devices of different diameters (col. 5 lines 1-9).

Regarding Applicant's arguments that Pruter ('614) lacks a slide configured to traverse the channel, the slide applying controlled clamping force on an accepted elongated medical device (Remarks p. 14, claim 24), the enclosed channel formed in part by the triangular groove 38, as cited in the prior Office Action, constitutes the claimed slide, wherein "slide" is interpreted to mean "a guiding surface along which something slides" as set forth by Merriam Webster.

9. Applicant's amendments are sufficient to overcome the previous drawing objection and rejection of claims 1-12 and 13-38 under 35 U.S.C. 112, 2nd paragraph.

Conclusion

10. The new grounds of rejection applied herein to claim 38 were not necessitated by Applicant's amendment; accordingly, this action is non-final.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to PARIKHA S. MEHTA whose telephone number is (571)272-3248. The examiner can normally be reached on M-F, 8 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571.272.4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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